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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/422,999 10/22/99 KAWASAKI

H MIT-103

021323 HM12/0726  
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EXAMINER

MURPHY, J

ART UNIT

PAPER NUMBER

1646

DATE MAILED:

14  
07/26/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

<b>Office Action Summary</b>	<b>Application No.</b> 09/422,999	<b>Applicant(s)</b> KAWASAKI ET AL.	
	<b>Examiner</b> Joseph F Murphy	<b>Art Unit</b> 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 May 2001.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2,4-7,9,11-118 and 120-130 is/are pending in the application.
- 4a) Of the above claim(s) 12-37,55-61,63-117 and 121-130 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 40-41, 46-49 is/are allowed.
- 6) ☒ Claim(s) 2, 4-7, 9, 11, 38-39, 42-45, 50-54, 118, 120 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other:  |

## **DETAILED ACTION**

### ***Formal Matters***

Claims 1, 3, 8, 10 and 119 were cancelled, claims 2, 4-7, 9, 11, 38-40, 45, 48, 50, 62, 118 and 120 were amended in paper No. 13, 5/21/2001. Claims 2, 4-7, 9, 11-118, and 120-130 are pending. Claims 12-37, 55-61, 63-117, 121-130 are withdrawn from consideration pursuant to 37 CFR 1.142(b). Claims 2, 4-7, 9, 11, 38-54, 62 118 and 120 are under consideration.

The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office Action.

### ***Response to Amendment***

The rejections to claims 1, 3, 8, 10 and 119 are rendered moot because the claims have been cancelled.

The rejection of claims 2-4, 9, 11, 38-39, 45, 48-54, 62, 118, 120 under 35 U.S.C 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid encoding a polypeptide with an amino acid sequence set forth in SEQ ID NO: 18, does not reasonably provide enablement for any other nucleic acid has been obviated by Applicant's amendment, and is thus withdrawn.

The rejection of claims 50-54 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a host cell in culture comprising a nucleic acid encoding an amino acid with the sequence as set forth in SEQ ID NO: 18, does not reasonably provide enablement for in vivo transfection has been obviated by Applicant's amendment, and is thus withdrawn.

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The rejection of claims 2-4, 9, 11, 38-39, 45, 48-54, 62, 118, 120 under 35 USC § 112, second paragraph as being indefinite in that they only describe the peptide of interest by an arbitrary protein name, i.e. cAMP-GEFII has been obviated by Applicant's amendment and is thus withdrawn.

***Claim Rejections - 35 USC § 112 first paragraph***

Claims 38-39 stand rejected, and amended claims 2, 4, 9, 11, 45, 118 are rejected, under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reasons of record set forth in Paper No. 11, 2/21/2001. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Applicant argues that the term variant is defined in the specification as sequences being 70-80% similar, or 60-70% identical to a disclosed sequence. This is therefore a genus claim. The specification and claims do not indicate what distinguishing attributes shared by the members of the genus. Thus, the scope of the claim includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. The specification and claims provide insufficient guidance as to what changes should be made. Structural features that could distinguish compounds in the genus from others in the protein class are missing from the disclosure. No common structural attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed.

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Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, SEQ ID NO: 17, encoding SEQ ID NO: 18, alone is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

Claims 118 and 120 stand rejected, and claims 42-45, 50-54 and 62 are rejected, under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for reasons of record set forth in Paper No. 11, 2/21/2001.

Applicant has amended the claim to remove the term "pharmaceutical preparation". However, the claims still read on gene therapy and are not enabled as set forth in the previous Office Action. Eck & Wilson demonstrate the numerous factors which complicate *in vivo* gene therapy with respect to predictably achieving levels and duration of gene expression which have not been shown to be overcome by routine experimentation. Claims 43-45, 50-54 and 62 are rejected insofar as they depend on claim 42.

***Claim Rejections - 35 USC § 112 second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 recites the term "stringent hybridization conditions", which is a conditional term and renders the claim indefinite. Furthermore, some nucleic acids which might hybridize under conditions of moderate stringency, for example, would fail to hybridize under conditions of high stringency. The metes and bounds of the claim thus cannot be ascertained. This rejection could be obviated by supplying specific conditions supported by the specification which Applicant considers to be "stringent".

***Claim Rejections - 35 USC § 102***

Claims 5-7 stand rejected under 35 U.S.C. 102(b) as being anticipated by Hillier et al. (1995) for reasons of record set forth in paper No. 11, 2/21/2001.

The nucleic acid taught by Hillier et al. comprises at least 15 consecutive nucleic acids of SEQ ID NO: 17, as shown in Sequence Comparison A, attached to Paper No. 11, 2/12/2001, therefore the claims are anticipated.

***Conclusion***

Claim 2, 4-7, 9, 11, 38-39, 42-45, 50-54, 118, 120 are rejected.


Claims 40-41, 46-49 are allowable.

***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph F. Murphy whose telephone number is 703-305-7245. The examiner can normally be reached on M-F 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 703-308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Joseph F. Murphy, Ph. D.  
Patent Examiner  
Art Unit 1646  
July 25, 2001

  
**PREMA MERTZ**  
**PRIMARY EXAMINER**